Proposed Updates to Regulation 61-36

Summer Forum - 2019

South Carolina Department of Health and Environmental Control

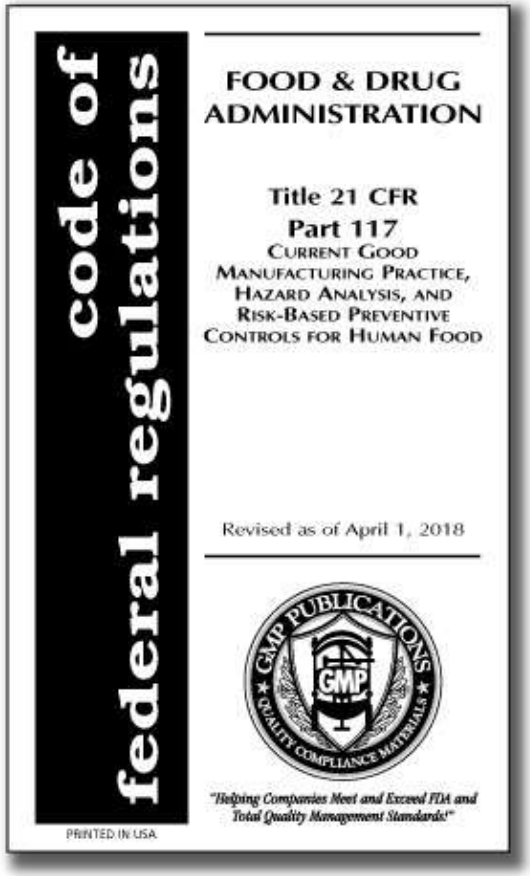
Healthy People. Healthy Communities.

Agenda

- Why Regulation 61-36 is Being Updated
- Process of Updating the Regulation
- What are “Manufactured Grade Dairy Products”
- The need to update and streamline the regulation to be more inclusive, and to provide for the regulation of other dairy based products such as cheese and butter.
- Elimination of 21 CFR 110 by the FDA as criteria for regulating food manufacturing facilities and the need to adopt the new 21 CFR 117 criteria and new preventive controls requirements
- Q & A
- Additional Forums + Meetings

Why Update the Regulation?

- Adopt by reference 21 CFR Part 117 to replace 21 CFR Part 110, which is obsolete
- The Department has identified a need to simplify and combine the existing regulations to create one regulation for all non-grade "A" milk products under the Department's jurisdiction
- Develop regulatory standards and requirements for manufacturing, storing, and distributing cheese and butter



Regulation Review Process

- Step #1 – Initial Staff Regulatory Revision Meetings
- Step #2 – Outreach to Industry and the Public (current step)
- Step #3 – Incorporate Industry and Public feedback into Revision
- Step #4 – Present to DHEC Board and Make Any Needed Amendments
- Step #5 – Present to the Legislature

What are “Manufactured Grade Dairy Products”?

- Non-Grade “A” Dairy based products that are not regulated by the PMO such as:
  - Ice Cream
  - Cheese
  - Butter
  - Imitation Milk

Today, we are starting the conversation with our ideas based upon:

- Current provisions of R.61-35 and R.61-36
- Our comparison of these regulations and the new 21 CFR 117 provisions
- The feedback we received from you during our inspections concerning modifications & clarifications needed in the current regulation, the process of properly manufacturing/storing cheese and butter, and ideas for the regulation of cheese and butter
- Nothing that follows is set in stone. We need your input before we develop a final draft proposal!

Updates Proposed by the Department

- R.61-36: "*Frozen Desserts*" → "*Manufactured Grade Dairy Products*"
- Add provisions of R.61-35 to updated R.61-36; Repeal R.61-35
- Routine surveillance sampling for all manufactured grade dairy products will be conducted at a frequency based on the product's level of risk
- Variance - Authorizes a modification or waiver of specific R.61-36 requirements if, in the Department's opinion, the variance will not result in a health hazard or nuisance
- Adopt by reference 21 CFR Part 117 and other product-relevant CFR's

21 CFR 110 vs. 21 CFR 117

- What has remained the same?
  - GMP's are mostly unchanged
- What are the major changes?
  - Preventive Controls and FSMA compliance for those facilities that are not exempted from CFR 117 altogether or considered a "qualified facility"

CFRs to Adopt by Reference

- **21 CFR Part 133** - Standards of identity for cheese
- **7 CFR Part 58** - Supplemental operational requirements for cheese and butter
- **21 CFR Part 101** - Food labeling requirements for all products

21 CFR Part 117 - Replacing 21 CFR Part 110

- All firms (registered with the FDA or not) must be in compliance with Subpart B.
- Firms registered with the FDA but that have attested and are a "qualified facility" must also be in compliance with parts A, D, and F. Firm should also be familiar with subpart E, compliance not necessary.
- Firms registered with the FDA that are not "qualified", must also be in compliance with Subparts C and G

What are Preventive Controls and who is exempt from them?

Key Facts about Preventive Controls for Human Food

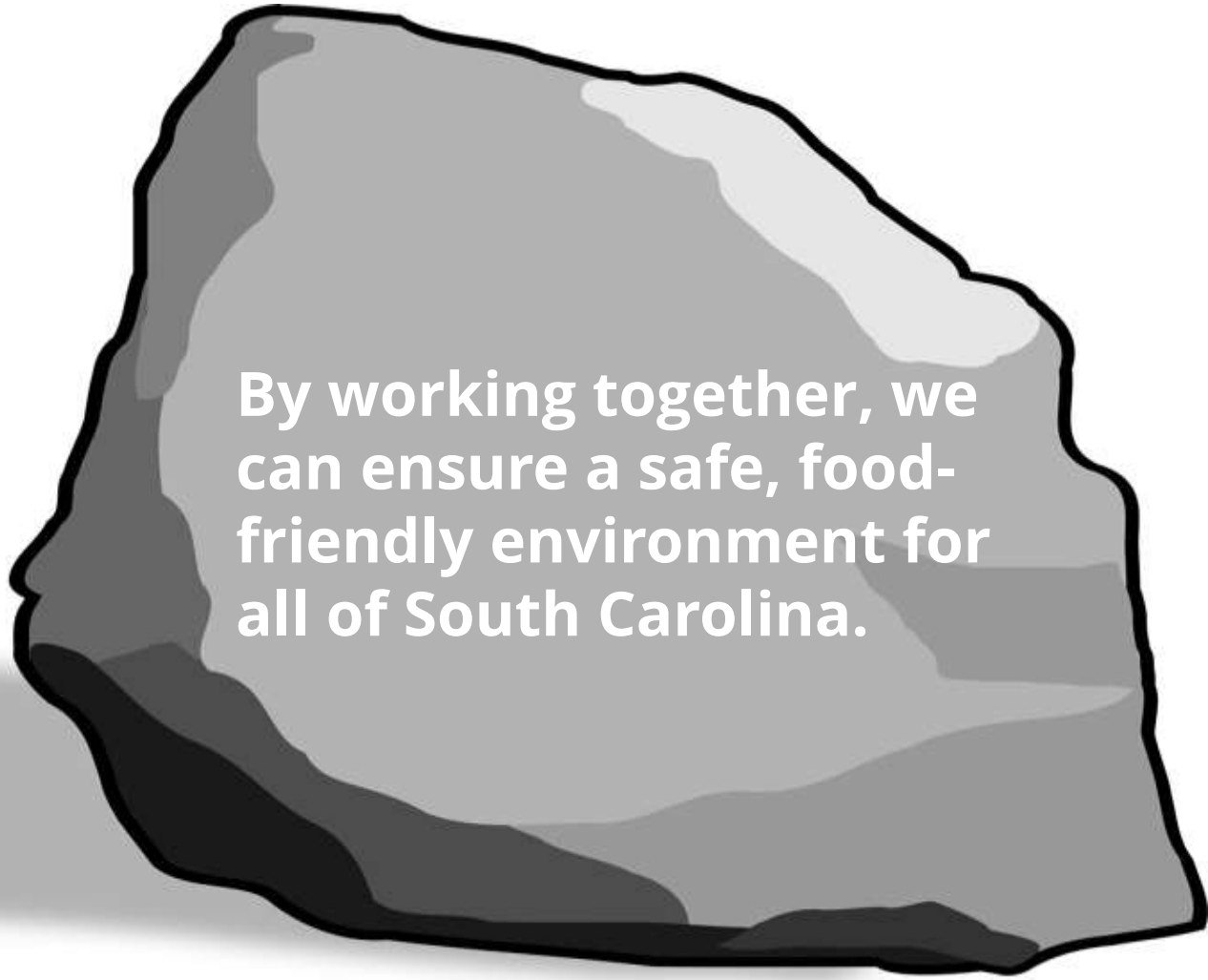
Preventive controls are steps that you, a domestic or foreign food facility, must take to reduce or eliminate food safety hazards. The rule on Preventive Controls for Human Food is mandated by the 2011 FDA Food Safety Modernization Act. The rule also incorporates the Current Good Manufacturing Practice (CGMP) requirements, which have been updated.

- DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?
- DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) APPLY TO ME?
- WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?
- WHAT CURRENT GOOD MANUFACTURING PRACTICES WERE UPDATED UNDER THIS RULE?
- WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?
- WHAT DO I DO IF A HAZARD COULD FIT UNDER DIFFERENT PREVENTIVE CONTROLS?
- WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?
- ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?

Nothing is Set in Stone

All we've discussed today are ideas; we need your input during the next month as we draft this revision!

We will come back out in the Fall, after the proposed revision is written, to get your comments and talk again before this goes to the legislature for approval.



Discussion?

If you'd like us to speak at a meeting of your association or group regarding the proposed regulation changes, please let us know!

South Carolina Department of Health and Environmental Control
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